UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	
Upsher-Smith Laboratories, Inc., a corporation,	)	**Docket No. 9297**
and	)	
American Home Products Corporation, a corporation.	)	

UPSHER-SMITH'S RESPONSE TO REPLY BRIEFS FILED BY COMPLAINT COUNSEL AND KV PHARMACEUTICAL

Even with a second round of briefing, Complaint Counsel and KV Pharmaceutical cannot support their assertions that Mark Robbins has responsibilities relating to competitive decisionmaking. Indeed, the additional evidence merely confirms that Mr. Robbins currently has responsibilities for providing legal advice on FDA regulations and intellectual property.

Complaint Counsel's Additional Evidence Does Not Show That Mr. Robbins Has Responsibility for Competitive Decisionmaking

On the very first page of their reply brief, Complaint Counsel appear to concede that Mr. Robbins should have access to Confidential Materials if his responsibilities involve "legal review and other functions normally performed by in-house counsel." As explained below and in the accompanying Supplemental Declaration of Mark S. Robbins, the evidence accompanying Complaint Counsel's reply brief demonstrates that Mr. Robbins's current responsibilities in fact constitute such "legal review and other functions normally performed by in-house counsel."

A. The Documents Submitted By Complaint Counsel Merely Confirm That Mr. Robbins Provides Legal Advice On Intellectual Property And FDA Regulations

Complaint Counsel first cite Therapeutic Strategies meetings (Exhs. A-C), but the notes of these meetings only confirm that Mr. Robbins's responsibilities relating to these meetings are legal in nature. The selected notes attached by Complaint Counsel — presumably the most damning in their eyes — indicate that Mr. Robbins was responsible for conducting three "patent search[es]" (Exh. B at 1, 2) evaluating "options which do not infringe Asacol patent" (Exh. B at 1) and meeting with "Dr. Pittelkow of Hy-Gene at Mayo" to conduct due diligence on intellectual property in connection with a potential in-licensing opportunity. (Exh. C at 2); Robbins Supp. Decl. ¶ 3. The Therapeutic Strategies notes thus reflect solely intellectual-property responsibilities. *See also* Robbins Decl. ¶¶ 3, 13, 14.

Complaint Counsel next cite certain monthly reports from Mr. Robbins to his boss (Exhs. D & E), but these documents also only confirm that Mr. Robbins's responsibilities are legal in nature. Both show unequivocally that Mr. Robbins is responsible for Upsher-Smith's interaction with the FDA and for compliance with FDA regulations (including review of clinical studies such as bioequivalent and pharmacokinetic studies to determine whether they satisfy FDA requirements). Robbins Supp. Decl. ¶ 4. These documents are perfectly consistent with earlier proof that Mr. Robbins has responsibilities for FDA regulatory matters — hardly surprising for the Chairman of the Food & Drug Section of the state bar association and an adjunct professor of Food & Drug Law. Robbins Decl. ¶¶ 2, 4, 5, 6, 10.

Complaint Counsel's Exhibits A-E, in short, confirm that Mr. Robbins is responsible for intellectual property issues and FDA regulatory issues, both the natural domain of an in-house counsel at any pharmaceutical company. By citing these documents, Complaint Counsel has

unless a legal issue (such as possible patent infringement) arose. *Id.* As to the second excerpt, it merely confirms Mr. Robbins's responsibilities related to FDA regulatory compliance.

Complaint Counsel also incorrectly asserts that Mr. Robbins has budgetary responsibility for the Research and Development budget. In fact, the R&D budget is developed by the Vice President of Operations (Chuck Woodruff) who has responsibility for managing R&D. Robbins Supp. Decl. ¶ 5. The R&D Budget is included in Upsher-Smith budget and planning documents under the heading of Scientific Affairs based on historical considerations and does not coincide with Mr. Robbins's responsibilities. *Id.*

All told, despite having voluminous Upsher-Smith documents, deposition transcripts of numerous Upsher-Smith witnesses and ample time to sort through it all, Complaint Counsel cannot offer any evidence undercutting Mr. Robbins's sworn statement that he does not have responsibility for competitive decisionmaking. In fact, the only evidence that Complaint Counsel can muster is evidence further establishing that Mr. Robbins's responsibilities are legal in nature.

KV Pharmaceutical's Reply Brief Offers No Additional Evidence

KV Pharmaceutical offers no new evidence, but instead desperately attempts to identify gaps in the language of Mr. Robbins's Declaration. KV Pharmaceutical first focuses on Mr. Robbins's statement that he does not have any "direct role or oversight" for product R&D, emphasizing "direct" to suggest that Mr. Robbins might have an "indirect" role. Mem. at 2. KV Pharmaceutical also asserts that the Declaration is silent as to whether Mr. Robbins has input into which products to develop. Mem. at 2. These attempts at flyspecking are baseless. The Declaration plainly disclaims categorically any role in R&D. "Direct role" and "oversight" were intended to cover the universe of responsibilities. If that were not clear enough, the point should also be clear from Paragraph 20 of the Declaration, which establishes that Mr. Robbins does not

have "any responsibility whatsoever for designing new products." Finally, Mr. Robbins confirms this point again in his Supplemental Declaration, where he also clarifies that his responsibilities differ dramatically from those of Mr. Mariani of KV Pharmaceutical. Robbins Supp. Decl. ¶ 7.

CONCLUSION

The moving parties raise understandable concerns over the preservation of confidential business materials. But those concerns must be weighed against the competing concern that Upsher-Smith be given a fair opportunity to defend itself in this proceeding. Your Honor already weighed these concerns in determining — over Complaint Counsel's objection — that designated in-house counsel would be given access to Confidential Materials as long as such counsel do not have responsibilities for competitive decisionmaking and as long as such counsel execute a declaration that they will not disclose or use the materials outside of this proceeding.

The evidence presented to Your Honor in these motions demonstrates that Mr. Robbins does ***not*** have responsibility for competitive decisionmaking. At most, the evidence offered by the moving parties shows that Mr. Robbins interacts regularly with executives who do engage in competitive decisionmaking. But all in-house counsel so interact with business executives. There is certainly no basis upon which to distinguish Mr. Robbins from his counterparts at Schering and AHP. He has similar responsibilities, he is similarly important to his company's defense of this action, and he will similarly execute a declaration binding himself, under penalty of law, to preserve the confidential information of KV Pharmaceutical and all other companies producing discovery in this proceeding.

For the reasons set forth above — as well as those set forth in Upsher-Smith's earlier memoranda and in Mr. Robbins's Declaration — the motions to amend the Protective Order should be denied. Mr. Robbins functions as an in-house attorney and Upsher-Smith should be

entitled to have him on their defense team, just as Schering and AHP have his counterparts on their defense teams.

Dated: June 18, 2001

Respectfully submitted,

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SUPPLEMENTAL DECLARATION OF MARK S. ROBBINS

I, Mark S. Robbins, hereby declare:

1. I submit this Supplemental Declaration to reconfirm that I do not have any responsibilities at Upsher-Smith for competitive decisionmaking, and to clarify certain issues raised in the reply briefs submitted by Complaint Counsel and KV Pharmaceutical. I also use this opportunity to re-commit to honoring my obligation to protect any confidential information to which I may gain access in this proceeding.

2. As to competitive decisionmaking, I do not have any role in R&D, marketing strategy, pricing or any other area where a competitor's confidential information would be potentially valuable. Those areas are strictly the responsibility of other individuals at Upsher-Smith. As I indicated in my earlier declaration, my responsibilities lie in providing legal advice on issues arising in regulatory affairs, clinical affairs, quality assurance, intellectual property, and product liability.

3. Complaint Counsel raise issues as to my role in Therapeutic Strategies meetings. To clarify, I can confirm that my role at these meetings is to report on, and to receive new assignments on, legal issues relating to Upsher-Smith's business.

These legal issues pertain to intellectual property matters (usually whether there are patent-infringement issues) as well as to regulatory matters (usually whether there are food-and-drug and labeling law obstacles to marketing a product). In my role of managing all of Upsher-Smith's intellectual property, I provide legal support on licensing activities, reviewing patent issues, assessing regulatory issues, and assisting in the drafting of contractual provisions. The Therapeutic Strategies notes provided by Complaint Counsel reflect the legal nature of my responsibilities in that Group by mentioning certain responsibilities relating to patent searches, patent infringement issues, and due diligence on intellectual property in connection with a licensing opportunity. Furthermore, I do not have responsibility for any of the areas reflected in the Product Prioritization Grid, but instead I use the priorities set by the business people to prioritize my responsibilities for assessing patent and regulatory issues. I emphasize that I am not consulted and do not participate on competitive issues such as what products to develop, what products to market, when to market them and what competitors already are or may later be in the market.

4. My two monthly reports provided by Complaint Counsel also reflect my legal-advisor role at Upsher-Smith. As these reports reflect, I am responsible for keeping business executives regularly informed as to progress and developments on regulatory issues. The reports provided by Complaint Counsel are typical in that they report on the status of FDA clearances, approvals and inquiries on products and labeling. I emphasize that my role in clinical trials is assuring that they are conducted and submitted in accordance with FDA rules and regulations.

I do not have responsibility for the strategic decisionmaking as to whether a particular product should be put through clinical trials.

5. Complaint Counsel also raise a question as to my budgeting responsibilities. To clarify, I do not have responsibility for the budgeting of R&D. That budgeting responsibility is upon Chuck Woodruff, Vice President of Operations, who supervises the R&D area. Complaint Counsel's confusion arises from the fact that the term "Scientific Affairs" in budgeting does not correlate to the same term in my title.

6. In discussing my deposition, I believe Complaint Counsel misreads my testimony. I never stated that "the group [I] supervise[]" was reformulating any product, as Complaint Counsel asserts. My actual testimony was that "[w]e" were reformulating the product, and by "we" I meant Upsher-Smith. I believe the context of my testimony confirms this intention, because going back to page 18 the line of questions related to Upsher-Smith generally rather then my group specifically. I can confirm categorically that neither I nor anyone reporting to me is responsible for reformulating any product. My group and I would only have a role in any reformulation if we were asked to assess patent-infringement issues or other legal or regulatory issues.

7. As to the declaration of Mr. Mariani at KV Pharmaceutical, I can confirm that it is apparent that his responsibilities differ greatly from mine. Mr. Mariani appears to have responsibility for R&D, Analytical Development and Quality Control at KV. At Upsher-Smith, these areas of responsibility report to Chuck Woodruff, Vice President - Operations. While there is some overlap between Mr. Mariani's

responsibilities and mine with respect to Regulatory Affairs and Clinical Affairs, it does not appear that Mr. Mariani has the same legal responsibilities for intellectual property, FDA compliance and product liability.

8. KV Pharmaceutical's reply brief suggests that I may have an "indirect" role in R&D, because I earlier denied only having a "direct role or oversight." My earlier statement was intended to be all-inclusive. To avoid any doubt, I now expressly deny having any indirect role in R&D.

9. As to KV Pharmaceutical's stated concern about clinical trials, I reiterate my earlier statement that my role in clinical affairs is limited to the legal aspect of safety and efficacy issues. My having access to confidential materials from KV Pharmaceutical or any other pharmaceutical company would not assist me in addressing legal issues arising in Upsher-Smith's clinical trials.

10. Finally, I would like to re-emphasize my intention to honor diligently my commitment to preserve the confidentiality of any Confidential Materials to which I am given access. I take my professional obligations seriously, and I can assure all interested parties that I will not improperly use or disclose any Confidential Materials. I will use the Confidential Materials merely to assist Upsher-Smith's outside counsel and authorized experts in understanding and interpreting the materials.

I declare under penalty or perjury that the foregoing is true and correct. Executed on June 18, 2001.

Mark S. Robbins

CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of June 2001 I caused copies of the foregoing Upsher-Smith's Response to Reply Briefs Filed by Complaint Counsel and KV Pharmaceutical to be served upon the following by hand delivery:

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